DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 26, 2015

NATEC Medical Ltd.
Xavier De Buchere
Regulatory Affairs & Quality Manager
Maeva Centre Building - Ebene Business Park
Silicon Avenue
Reduit 72201, Mauritius

Re: K141933
Trade/Device Name: Filao NC RX PTCA Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: May 28, 2015
Received: May 29, 2015

Dear Xavier De Buchere,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141933

Device Name
Filao NC RX PTCA Dilatation catheter

Indications for Use *(Describe)*
The Filao NC RX PTCA Dilatation Catheters are indicated for:

Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion.

Balloon dilatation of a stent after implantation (balloon models 2.00mm - 4.50mm)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K141933 510(K) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Applicant: Natec Medical Ltd.
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Summary Preparation Date: June 25, 2015

Device Name:

Trade Name:	Filao NC RX PTCA Dilatation Catheter
Common/Usual Name:	PTCA Catheter
Classification Name:	Percutaneous transluminal coronary angioplasty catheter
Generic name:	PTCA Catheter
Regulation Number:	870.5100
Product Code:	LOX
Device Class:	Class II

Predicate Devices:

- Tamarin Blue PTCA Dilation catheter – K112735
- NC Trek - Abbott Vascular Inc. – K110134

Device Description:

The Filao NC RX PTCA Dilatation Catheter is a standard Rapid Exchange (RX) PTCA catheter with a non-compliant inflatable balloon at the distal part and an atraumatic, tapered tip to aid in crossing the tight stenosis. Two radiopaque markers facilitate proper balloon positioning across the stenosis, and a hydrophilic coating improves pushability of the catheter.

The Filao NC PTCA RX Catheter is available in balloon diameters ranging from 2.00 mm to 4.50 mm, and balloon lengths ranging from 8mm to 30 mm in step of 1 mm. The maximum recommended guide wire diameter is 0.014"

Device Intended Use:

The Filao NC RX PTCA Dilatation Catheters are indicated for:

- Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion.
- Balloon dilatation of a stent after implantation (balloon models 2.00mm - 4.50mm).

Comparison of Technical Characteristics:

The design, materials and manufacturing of the Filao NC RX PTCA Dilatation Catheter are the same or similar to those of used for the predicate devices. The indication for use for the Filao NC RX PTCA Dilatation Catheter is also comparable to the predicate devices.

Performance Data:

Substantial Equivalence has been demonstrated based on the results of non-clinical testing on the Filao NC RX PTCA Dilatation Catheter which addressed the following considerations:

- Catheter dimensions and balloon profile
- Balloon preparation, deployment and retraction
- Balloon rated burst pressure (within a stent)
- Balloon compliance
- Balloon fatigue (within a stent)
- Balloon inflation and deflation time
- Bond strengths
- Tip pull test
- Flexibility and kink test
- Torque strength test
- Coating integrity test
- Particulate Evaluation test

Conclusion:

Based on the similarities in the indication for use, device design and materials, and the results of the non-clinical testing and analysis, the Filao NC RX PTCA Dilatation Catheter is considered substantially equivalent to the aforementioned predicate devices.